PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 12 February 2001 (12.02.01)	
International application No. PCT/GB00/01633	**Applicant's or agent's file reference** SMK/LP5848023
International filing date (day/month/year) 27 April 2000 (27.04.00)	**Priority date** (day/month/year) 28 April 1999 (28.04.99)
Applicant CHRISTOU, Paul et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

21 November 2000 (21.11.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

09/980,650

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Olivia TEFY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

PATENT COOPERATION TREATY

REC'D 13 JUL 2001
WIPO PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70) 14

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SMK/LP5848023		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/01633	27/04/2000	28/04/1999
International Patent Classification (IPC) or national classification and IPC C12N15/62		
Applicant PLANT BIOSCIENCE LIMITED		

09/980,650

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21/11/2000	11.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Trommsdorff, M Telephone No. +49 89 2399 7361

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01633

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-53 as originally filed

Claims, No.:

1-41 as originally filed

Drawings, sheets:

1/21-21/21 as originally filed

Sequence listing part of the description, pages:

1-15, filed with the letter of 19.07.2000

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2, 3, 9, 11, 12, 18, 23-32, 36, 37, 41
	No:	Claims	1, 4-8, 10, 13-17, 19-22, 33-35, 38-40
Inventive step (IS)	Yes:	Claims	2, 3, 9, 11, 12, 18, 23-32, 36, 37, 41
	No:	Claims	1, 4-8, 10, 13-17, 19-22, 33-35, 38-40
Industrial applicability (IA)	Yes:	Claims	1-41
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Cited documents

The following documents (D) are referred to in this communication; the numbering is the same as in the search report and will be adhered to in the rest of the procedure:

D1: WO 98 18820 A (UNIV SOUTH CAROLINA) 7 May 1998 (1998-05-07)
D2: WO 96 10083 A (CIBA GEIGY AG) 4 April 1996 (1996-04-04)
D3: US-A-5 668 255 (MURPHY JOHN R) 16 September 1997 (1997-09-16)
D4: US-A-5 763 245 (GREENPLATE JOHN T ET AL) 9 June 1998 (1998-06-09)

2. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The present application describes fusion proteins having binding and toxic domains wherein the binding domain is derived from a lectin domain from the ricin toxin and the toxin is derived from *Bacillus thuringiensis* cry toxin. Also described are nucleic acids encoding said proteins and methods of producing transgenic plants expressing said fusion products.

2.1. Although none of the available prior art documents specifically discloses fusion proteins comprising a lectin domain fused to a cry toxin domain, the claims are so broadly formulated that the teachings of several prior art documents fall into their scope.

D1 describes ricin fusion proteins for cancer treatment, wherein a mutated lectin binding domain of the ricin galactose-binding B chain (RTB) is fused to the ricin toxin A chain binding non-specifically to cell surface sugars or to a ligand specific for a particular cell surface receptor, such as, e.g. IL-2 binding specifically to the IL-2 receptor (p.26-48, examples I-III). The authors show that the RTB mutants have a reduced binding affinity to sugars compared to wild-type RTB (p.30, l.19-25). Mice were injected with different fusion proteins containing one to several mutations in the lectin binding domain. Results show that mice tolerated more toxin when injected with triple RTB mutants compared to single RTB mutants

(p.35, l.1- p.36, l.5). Thus, the nucleic acid molecules encoding the fusion proteins described in D1 contain all the technical features of claim 1 and are thus novelty destroying to said claim and dependent claims 4-8 (Art. 33(1) and (2) PCT). Consequently, related claims 13-15 directed to a method of producing said fusion proteins, claims 16, 17 and 19 directed to a recombinant vector comprising said nucleic acid molecule and claims 20- 22 and 33-35 are also not novel (Art. 33(1) and (2) PCT).

2.2. D3 describes fusion proteins comprising a binding domain and a toxin domain from two different organisms. In example 2 (columns 9-11; Fig.1) a hybrid gene encoding the cholera toxin A1-diphteria toxin B'-IL2 domains is produced. Said gene has all the technical features of the nucleic acid molecule of claim 1. Moreover, the sequence alignment shows that the sequence of D3 (Fig. 11A/B) shares 99.3% identity in 813 bp overlap with sequence ID no 3, 99.4% identity in 713 bp overlap with sequence ID no 4 and 97.3% identity in 476 bp overlap with sequence ID no 5 of the application. Thus, the nucleic acid molecule of D3 is novelty destroying to the subject-matter of claims 1, 10 and related claims 13, 16, 17, 20- 22 and 33-35 (Art. 33(1) and (2) PCT).

2.3. D4 describes methods of controlling insects by treating plants with 3-hydroxysteroid oxidase in combination with cryIA (b) or cryIA(c). The vectors comprising said genes are inserted by bombardment of embryogenic tissue culture cells and transformed cells are selected and regenerated to whole plants which can then be tested by Western blot or esterase activity assay (column 19, l.30-37). Said method contains all the technical features of the method of claims 38-40 and is thus novelty destroying to said claims (Art. 33(1) and (2) PCT).

3. Re Item VII
Certain defects in the international application

3.1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

4. Re Item VIII

Certain observations on the international application

4.1. The relative terms "degeneratively equivalent" used in claims 9-11 or "homologous variant" used in claim 12 have no well-recognised meaning and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claims unclear (Art. 6 PCT). Said nucleic acid molecules or parts of (see claims 10 and 11) need to be further defined by a functional feature, i.e. their function as a toxin or a ligand binding domain.

4.2. Claims 14 and 15 are directed to methods of modifying the sequence of the claimed nucleic acid molecule. Here again, the modified molecule needs to be further defined by a functional feature since any molecule could be obtained given enough substitutions, additions etc (Art. 6 PCT).

4.3. The relative term "commodity" used in claim 36 has no well-recognised meaning and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Art. 6 PCT).

WO 00/66755
PCT/GB00/01633

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
KREMER, Simon, M.
Mewburn Ellis
York House
23 Kingsway
London WC2B 6HP
ROYAUME-UNI

RECEIVED
20 NOV 2000

Date of mailing (day/month/year) 09 November 2000 (09.11.00)		
Applicant's or agent's file reference SMK/LP5848023		**IMPORTANT NOTICE**
International application No. PCT/GB00/01633	**International filing date** (day/month/year) 27 April 2000 (27.04.00)	**Priority date** (day/month/year) 28 April 1999 (28.04.99)
Applicant PLANT BIOSCIENCE LIMITED et al		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AG,AU,DZ,KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
   GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
   NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   09 November 2000 (09.11.00) under No. WO 00/66755

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

09/743590

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
SMK/LP5848023		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 00/ 01633	17/04/2000	28/04/1999
Applicant		
PLANT BIOSCIENCE LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [X] furnished subsequently to this Authority in written form.

   [X] furnished subsequently to this Authority in computer readble form.

   [X] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Disclosed are polynucleotides encoding a pesticidal fusion polypeptide comprising (i) a toxin domain;and (ii) a heterologous binding domain capable of binding non-specifically to a cell membrane without disrupting that membrane. Preferably the toxin domain is derived from a Bacillus thuringiensis cry toxin (e.g. CryIA (b) or (c)) and the binding domain is derived from a lectin (e.g. ricin toxin B chain). The use of such fusions may help to inhibit the acquisition of resistance in a pest population treated with the polypeptide. A further aspect of the invention is a method of assessing the toxicity of a polypeptide to a pest species by expressing a nucleic acid encoding said polypeptide in a host cell from that species, observing the viability of the cell and correlating the results of the observation with the toxicity of the polypeptide, wherein the viability is determined by assessing esterase activity or membrane integrity.

INTERNATIONAL SEARCH REPORT

Interna[redacted]al Application No
PC[redacted] 00/01633

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/62 C07K14/32 C07K14/415 A01N63/00 C12N15/10
C12N15/63 C12N15/866 C12N5/14 C12P21/00 C12Q1/00
C12N15/82

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K C12N A01N C12P C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, STRAND

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 18820 A (UNIV SOUTH CAROLINA) 7 May 1998 (1998-05-07) the whole document ---	1,4-8, 13-17, 19-23, 26-28, 31,33-35
X	WO 96 10083 A (CIBA GEIGY AG) 4 April 1996 (1996-04-04) page 10, line 22 - line 33 page 26, line 29 -page 27, line 2 page 31, line 1 - line 14 page 27, line 24 -page 28, line 18 --- -/--	1,2,4, 13-17, 19-35,37

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 November 2000	22/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Schönwasser, D

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna[redacted]al Application No
PC[redacted] 00/01633

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 668 255 A (MURPHY JOHN R) 16 September 1997 (1997-09-16) column 2, line 29 -column 3, line 14; claims 1,3,4,9,17	1,10,13
X	US 5 763 245 A (GREENPLATE JOHN T ET AL) 9 June 1998 (1998-06-09) column 1, line 26 - line 47 column 19, line 34 - line 37	38-40
A	PATENT ABSTRACTS OF JAPAN vol. 018, no. 542 (C-1261), 17 October 1994 (1994-10-17) & JP 06 192295 A (TOAGOSEI CHEM IND CO LTD), 12 July 1994 (1994-07-12) abstract	1,2,13
A	RAJEMOHAN F. ET AL.: "Bacillus thuringiensis insecticidal proteins: molecular mode of action" PROGRESS IN NUCLEIC ACID RESEARCH AND MOLECULAR BIOLOGY, vol. 60, 1998, pages 1-27, XP000926040 the whole document	1-41

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/[redacted] 00/01633

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9818820 A	07-05-1998	AU 5003597 A	22-05-1998
WO 9610083 A	04-04-1996	US 5849870 A	15-12-1998
		AU 692934 B	18-06-1998
		AU 3743395 A	19-04-1996
		BG 101384 A	31-10-1997
		BR 9509099 A	30-09-1997
		CA 2199049 A	04-04-1996
		CN 1160420 A	24-09-1997
		EP 0792363 A	03-09-1997
		HU 77449 A	28-04-1998
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		TR 960263 A	21-06-1996
		US 6107279 A	22-08-2000
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		US 5990383 A	23-11-1999
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		US 5840868 A	24-11-1998
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		US 5965406 A	12-10-1999
		AU 657087 B	02-03-1995
		AU 7168991 A	24-07-1991
		AU 8032194 A	27-04-1995
		CA 2071969 A	23-06-1991
		EP 0439954 A	07-08-1991
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		NO 922447 A	19-08-1992
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		AT 79136 T	15-08-1992
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		ES 8708014 A	16-11-1987
		ES 557103 D	16-12-1987
		ES 8801376 A	01-03-1988
		FI 860541 A	06-02-1986
		JP 6205684 A	26-07-1994
		JP 2510984 B	26-06-1996
		JP 61502304 T	16-10-1986
		NO 176807 B	20-02-1995
		NZ 212312 A	29-09-1988
		WO 8600090 A	03-01-1986
US 5763245 A	09-06-1998	US 5558862 A	24-09-1996
		US 5554369 A	10-09-1996
		US 5518908 A	21-05-1996
		AT 147231 T	15-01-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 00/01633

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5763245 A		AU 686200 B	05-02-1998
		AU 7214094 A	24-01-1995
		BR 9406965 A	27-08-1996
		CA 2163120 A	12-01-1995
		CN 1126423 A	10-07-1996
		DE 69401436 D	20-02-1997
		DE 69401436 T	26-06-1997
		DK 706320 T	07-07-1997
		EP 0706320 A	17-04-1996
		ES 2097656 T	01-04-1997
		GR 3023050 T	30-07-1997
		HU 73324 A	29-07-1996
		JP 9500528 T	21-01-1997
		NZ 268794 A	27-08-1996
		PL 312277 A	15-04-1996
		WO 9501098 A	12-01-1995
		MX 9205383 A	01-03-1993
JP 06192295 A	12-07-1994	NONE	